## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 5, 2011 has been entered.

### *Claim Rejections 35 U.S.C. 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4, 6-18, 23-33, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maciazek et al. in view of Gander (US 4,323,581).

3. Maciazek et al. teaches that Retinoid-induced repression of HIV core promoter activity inhibits virus replication. Retinoid particularly inhibit the infection of cells. Further it is known that the rate of mother to child transmission of HIV-1, progression to AIDS from HIV-1 infection, and AIDS-associated mortality are all inversely correlated with serum vitamin A levels. Maciazek particularly teaches that retinol or its metabolite repress HIV-1 replication. See, particularly, the abstract, pages 5863-5866.

4. Maciazek et al. do not teach expressly the employment of 4-HPR for treating HIV infection or for inhibiting HIV infection to cells.

5. However, Gander et al. teaches that 4-HPR is a retinoid derivative, with the function of retinoid, but with low systemic toxicity. See, particularly, col. 1, line 38 to col. 2, line 53.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use 4-HPR as a retinoid for treating HIV infection or for inhibiting HIV infection of cells.

A person of ordinary skill in the art would have been motivated to use 4-HPR as a retinoid for treating HIV infection or for inhibiting HIV infection of cells because 4-HPR is a known retinoid derivative with low systemic toxicity. As to the functional limitations "inhibiting a viral attachment/entry or exit phase of a virus" recited in claim 23, note, the recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Further, the instant claims are directed to affecting a biochemical pathway with old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (inhibiting HIV infection in cell) for the compounds, e.g., retinoid compounds, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a

claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Furthermore, the further employment of other known anti-HIV agents for the treatment of HIV infection would have been obvious to one of ordinary skill in the art, as it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known anti-HIV agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Finally, the optimization of a result effective parameter, e.g., effective amount of a therapeutic agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. The limitation recited in claim 23 and the newly added claim 37 are drawn to particular biological function or process, which do not materially affect the claimed method. As discussed above, such limitations do not carrier much patentable weight.

***Response to the Arguments***

Applicants' amendments and remark submitted May 5, 2011 have been fully considered, but are not persuasive.

Applicants contend that the rejections above fails to establish a *prima facie* case of obviousness as Maciaszek et al. do not teach that retinoid induces repression of HIV core

promoter activity, HIV infection, and HIV replication in ***all*** cells. The arguments are not persuasive. Assume that applicants' statement "Maciaszek et al. do not teach that retinoid induces repression of HIV core promoter activity, HIV infection, and HIV replication in ***all*** cells." is true, it will not negate the motivation of ordinary skill in the art to use retinoid for treating HIV patients because retinoid at least will suppress HIV infection, (or inhibit HIV replication, suppress the entry of HIV) in uninfected cells. As it is well settled that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1627

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